

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

NOVARTIS AG
Lichtstrasse 35
CH-4056, Basel
Switzerland

and

NOVARTIS VACCINES
AND DIAGNOSTICS, INC.
4560 Horton Street
Emeryville, California 94608

Plaintiffs,

v.

HON. DAVID J. KAPPOS
Under Secretary of Commerce for Intellectual
Property and Director of the United States Patent
and Trademark Office

Office of the General Counsel
United States Patent and Trademark Office
P.O. Box 15667, Arlington, VA 22215
Madison Building East, Room 10B20
600 Dulany Street, Alexandria, VA 22314

Defendant.

Civil Action No. _____

Case: 1:10-cv-01138
Assigned To : Urbina, Ricardo M.
Assign. Date : 7/6/2010
Description: General Civil

COMPLAINT

Plaintiff Novartis AG and Plaintiff Novartis Vaccines and Diagnostics, Inc. ("Novartis" or "Plaintiffs"), for their complaint against the Honorable David J. Kappos (hereinafter "Kappos" or "Defendant"), states as follows:

NATURE OF THE ACTION

1. This is an action by Novartis, the owner and assignee of United States Patent Nos.

6,656,957; 6,878,721; 7,098,325; 7,112,673; 7,265,089; 7,348,353; 7,423,148; 7,470,709; 7,470,792; 7,534,890; and 7,576,221 (collectively, the “Novartis Patents”) for review of the determination by Defendant, pursuant to, *inter alia*, 35 U.S.C. § 154(b)(3)(B), of the patent term adjustment of each of the Novartis Patents. Novartis seeks a judgment that the patent term for each of the Novartis Patents be increased¹ as reflected in the attached Exhibit A.

2. This action arises under 35 U.S.C. § 154, the Fifth Amendment of the Constitution of the United States, and the Administrative Procedure Act, 5 U.S.C. §§ 701-706.

THE PARTIES

3. Novartis AG is a corporation organized and existing under the laws of Switzerland, with its principal place of business at Lichtstrasse 35, CH-4056, Basel, Switzerland.

4. Novartis Vaccines and Diagnostics, Inc. is a corporation organized and existing under the laws of Delaware with its principal place of business at 4560 Horton Street, Emeryville, California 94608. Novartis Vaccines and Diagnostics, Inc. is a wholly-owned subsidiary of Novartis AG.

5. Kappos is the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (“PTO”), acting in his official capacity. The Director is the head of the PTO and is responsible for superintending or performing all duties required by law with respect to the granting and issuing of patents, and is designated by statute as the official responsible for determining the period of patent term adjustments under 35 U.S.C. § 154(b)(3)(B).

JURISDICTION AND VENUE

6. This Court has jurisdiction to hear this action and is authorized to issue the relief

¹ In the case of United States Patent No. 7,423,148, the PTA granted by the PTO actually should be decreased, but the decrease should be offset and limited by a period of B Delay that the PTO failed to aggregate to the period of A Delay when calculating total PTO delay.

sought pursuant to 28 U.S.C. §§ 1331, 1338(a), 1361, 2201 & 2202; 35 U.S.C. § 154(b)(4)(A); and 5 U.S.C. §§ 701-706.

7. Venue is proper in this district by virtue of 35 U.S.C. § 154(b)(4)(A).

8. This Complaint is being timely filed, *inter alia*, in accordance with 35 U.S.C. § 154(b)(4)(A) and, alternatively, pursuant to the doctrine of equitable tolling and/or in compliance with the discovery rule.

ALLEGATIONS COMMON TO ALL COUNTS

The Novartis Patents

9. Novartis is the assignee of all right, title and interest in the Novartis Patents, as evidenced by records on deposit with the PTO and the face of each of the Novartis Patents attached hereto as Exhibits B-L. As such, Novartis is the real party in interest in this case.

10. Calculation of the appropriate patent term for each of the Novartis Patents based upon the relevant prosecution history of each of these patents is summarized in Exhibit A.

Patent Term Guarantee

11. The Patent Term Guarantee Act of 1999, a part of the American Inventors Protection Act, amended 35 U.S.C. § 154(b) to address concerns that delays by the PTO during the prosecution of patent applications could result in a shortening of the effective life of the resulting patents to less than seventeen years.

12. Amended 35 U.S.C. § 154(b) broadened the universe of cognizable administrative delays by the PTO that could retroactively yield an extension of the patent term to compensate for such prosecution delays ("Patent Term Adjustment" or "PTA").

13. Patent Term Adjustment applies to original utility patent applications (including continuations, divisionals and continuations-in-part) filed on or after May 29, 2000.

14. In calculating PTA, Defendant must take into account PTO delays under 35 U.S.C. § 154(b)(1), any overlapping periods in the PTO delays under 35 U.S.C. § 154(b)(2)(A), and any applicant delays under 35 U.S.C. § 154(b)(2)(C).

15. Under 35 U.S.C. § 154(b)(1)(A), an applicant is entitled to PTA for the PTO's failure to carry out certain acts during processing and examination within defined deadlines ("A Delay").

16. Under 35 U.S.C. § 154(b)(1)(B), an applicant is entitled to additional PTA attributable to the PTO's "failure . . . to issue a patent within 3 years after the actual filing date of the application in the United States," but not including "any time consumed by continued examination of the application requested by the applicant under section 132 (b)" ("B Delay").

17. 35 U.S.C. § 154(b)(2)(A) provides that "to the extent that periods of delay attributable to grounds specified in paragraph [154(b)(1)] overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed."

18. 35 U.S.C. § 154(b)(2)(C)(i) directs that "the period of adjustment of the term of a patent under paragraph [154(b)(1)] shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." ("C Reduction").

Defendant's Abrogation of the Patent Term Guarantee

19. Upon information and belief, Defendant consistently calculated PTA for utility patent applications filed at least as early as May 29, 2000 that resulted in issued patents at least as late as March 1, 2010 in a manner that incorrectly determined the overlap of A Delay and B Delay.

20. Defendant had improperly contended that the period of B Delay began to accrue from the filing date of the patent application, rather than from three years after the filing date of the patent application.

21. Consequently, Defendant had considered the overlap of A Delay and B Delay to include any period of A Delay within the first three years after filing a patent application.

22. Accordingly, Defendant's policy and practice in calculating PTO delay was to grant PTA amounting to the greater of A Delay or B Delay.

23. This policy and practice often had the effect of depriving a patentee of patent term to which it was entitled under 35 U.S.C. § 154(b).

The Federal Circuit Decision in Wyeth v. Kappos

24. On January 7, 2010, the Court of Appeals for the Federal Circuit in Wyeth v. Kappos, 591 F.3d 1364 (Fed. Cir. 2010) ("Wyeth"), affirmed the District Court ruling in Wyeth v. Dudas, 580 F. Supp. 2d 138 (D.D.C. 2008), that Defendant's policy and practice of granting PTA amounting to the greater of A Delay or B Delay violated 35 U.S.C. § 154(b)(2)(A).

25. The Federal Circuit held that in determining the overlap of A Delay and B Delay when calculating PTA, Defendant should have aggregated A Delay and B Delay except to the extent that such aggregation would have amounted to counting the same calendar days twice.

26. On January 21, 2010, the PTO announced that it would not seek further review of the Wyeth decision but, rather, would prepare guidance for expediting requests for recalculation of PTA consistent with this decision.

Defendant's Implementation of Remedial Measures in Light of Wyeth v. Kappos

27. On January 28, 2010, the PTO announced interim procedures for patentees to request PTA recalculation in light of Wyeth. These interim procedures included an expedited,

informal procedure for seeking recalculation of PTA solely on the basis of Wyeth, but extended that remedy only to patents issued on or after September 2, 2009.

28. Defendant has not provided and will not voluntarily provide a remedy for the recalculation of PTA for a utility patent deprived of patent term due to Defendant's policy and practice of violating 35 U.S.C. § 154(b)(2)(A) as determined in Wyeth if such utility patent arose from an application filed by May 29, 2000 and issued on or before September 1, 2009 ("Older Issued Patents").

29. Defendant's refusal to accord the benefits of Wyeth to Older Issued Patents is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and in excess of statutory jurisdiction, authority or limitation.

The Impact of Such Remedial Measures on the Novartis Patents

30. Each of the Novartis Patents is an Older Issued Patent.

31. Each of the Novartis Patents has been deprived of patent term in an amount reflected in Exhibit A due to Defendant's policy and practice of violating 35 U.S.C. § 154(b)(2)(A) as determined in Wyeth.

32. Defendant will not afford Novartis an administrative remedy to recapture patent term of which it was deprived consistent with Wyeth for any of the Novartis Patents.

33. Defendant contends that despite this inequity, it is improper to entertain or grant a recalculation of PTA pursuant to Wyeth for the Novartis Patents because Defendant is constrained by 35 U.S.C. § 154(b)(4)(A) to afford a recalculation of PTA to Older Issued Patents.

34. Under 35 U.S.C. § 154(b)(4)(A), "[a]n applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director

filed in the United States District Court for the District of Columbia within 180 days after the grant of the patent. Chapter 7 of title 5 shall apply to such action."

CLAIMS FOR RELIEF

COUNT ONE
(Patent Term Adjustment Under 35 U.S.C. § 154)

35. The allegations of paragraphs 1-34 are incorporated in this claim for relief as if fully set forth herein.

36. The 180 day limitation period set forth in 35 U.S.C. § 154(b)(4)(A) applies to a re-determination of PTA by Defendant under "paragraph (3)," i.e., 35 U.S.C. § 154(b)(3).

37. 35 U.S.C. § 154(b)(3), by its plain terms, governs a PTA determination by Defendant only in conjunction with a notice of allowance of a patent application.

38. 35 U.S.C. § 154(b)(3) does not cover a PTA determination by Defendant in conjunction with the issuance of a patent.

39. Due to the narrow scope of 35 U.S.C. § 154(b)(3), the limitation period in 35 U.S.C. § 154(b)(4)(A) does not restrict the time within which a patentee, through a civil action in this District, may appeal a PTA determination by Defendant made contemporaneous with the grant of a patent.

40. In this action, Novartis is seeking a recalculation of PTA for each of the Novartis Patents determined by Defendant upon issuance of each of these patents.

41. The 180 day limitation period set forth in 35 U.S.C. § 154(b)(4)(A) is inapplicable to Novartis' claim herein.

42. Novartis is not time barred by 35 U.S.C. § 154(b)(4)(A) in appealing the PTA determination by Defendant as to each of the Novartis Patents.

43. Novartis is entitled to additional patent term consistent with Wyeth for each of the

Novartis Patents as reflected in Exhibit A.

COUNT TWO
(Equitable Tolling)

44. The allegations of paragraphs 1-43 are incorporated in this claim for relief as if fully set forth herein.

45. Even if the 180 day limitation period set forth in 35 U.S.C. § 154(b)(4)(A) is applicable to Novartis' claim herein, it is a non-jurisdictional statute of limitations.

46. The equitable tolling doctrine is a creation of common law that has been read into every statute of limitations.

47. Novartis lacked knowledge and adequate notice of its claim that Defendant had been improperly interpreting 35 U.S.C. § 154(b)(2)(A) in calculating the overlap of A Delay and B Delay and, thus, the appropriate patent term of each of the Novartis Patents until Defendant's announcement that the PTO would not appeal the Wyeth decision or, at the earliest, the date of the decision itself.

48. Novartis justifiably relied to its detriment upon Defendant's consistent and long standing, yet flawed, interpretation of 35 U.S.C. § 154(b)(2)(A) in calculating the overlap of A Delay and B Delay to determine PTA in failing to raise such a claim as to the Novartis Patents prior to Defendant's concession that the PTO would abide by the Wyeth decision, or at least prior to the Wyeth ruling.

49. Accordingly, the 180 day limitation period set forth in 35 U.S.C. § 154(b)(4)(A) should be equitably tolled from at least January 7, 2010, but from no later than January 21, 2010.

50. Novartis is entitled to additional patent term consistent with Wyeth for each of the Novartis Patents as reflected in Exhibit A.

**COUNT THREE
(Discovery Rule)**

51. The allegations of paragraphs 1-50 are incorporated in this claim for relief as if fully set forth herein.

52. The discovery rule, which governs a claim's accrual date for statute of limitations purposes, is distinct from equitable tolling.

53. Indeed, the discovery rule is to be applied in all federal question cases in the absence of a contrary directive from Congress.

54. The deprivation of patent term for each of the Novartis Patents resulting from Defendant's failure to properly determine the overlap of A Delay and B Delay under 35 U.S.C. § 154(b)(2)(A) was not the sort of injury that could readily have been discovered by Novartis at the time of the deprivation due to Defendant's consistent policy and practice of incorrectly interpreting and implementing this statutory provision by granting PTA amounting to the greater of A Delay or B Delay.

55. Novartis discovered, and with due diligence should have discovered, the deprivation of patent term for each of the Novartis Patents resulting from Defendant's failure to properly determine the overlap of A Delay and B Delay under 35 U.S.C. § 154(b)(2)(A) only when Defendant announced that the PTO would not appeal the Wyeth decision or, at the earliest, the date of the decision itself.

56. Accordingly, the 180 day limitation period set forth in 35 U.S.C. § 154(b)(4)(A) commenced on January 21, 2010, but no earlier than on January 7, 2010.

57. Novartis is entitled to additional patent term consistent with Wyeth for each of the Novartis Patents as reflected in Exhibit A.

COUNT FOUR
(Violation of the Fifth Amendment of the Constitution of the United States)

58. The allegations of paragraphs 1-57 are incorporated in this claim for relief as if fully set forth herein.

59. The Fifth Amendment of the Constitution of the United States provides in relevant part, “[N]or shall private property be taken for public use, without just compensation.”

60. Novartis enjoys a substantial and cognizable private property right in the full and complete term of each of the Novartis Patents.

61. Novartis has paid all necessary maintenance fees to the PTO required to maintain its rights in each of the Novartis Patents.

62. In calculating overlap of A Delay and B Delay pursuant to 35 U.S.C. § 154(b)(2)(A) when determining PTA for each of the Novartis Patents, Defendant granted PTA amounting to the greater of A Delay or B Delay.

63. Defendant's improper calculation of overlap of A Delay and B Delay when determining PTA for each of the Novartis Patents permanently deprived Novartis of patent term for each of the Novartis Patents to which it was entitled under 35 U.S.C. § 154(b) as reflected in the Wyeth decision.

64. Defendant's purposeful and deliberate diminution of the patent term of each of the Novartis Patents constitutes a taking of Novartis' property without just compensation, in violation of the Fifth Amendment of the Constitution of the United States.

COUNT FIVE
**(Declaratory Judgment Under The Administrative Procedures Act,
5 U.S.C. § 702 et seq.)**

65. The allegations of paragraphs 1-64 are incorporated in this claim for relief as if fully set forth herein.

66. In calculating overlap of A Delay and B Delay pursuant to 35 U.S.C. § 154(b)(2)(A) when determining PTA for each of the Novartis Patents, Defendant granted PTA amounting to the greater of A Delay or B Delay.

67. Defendant's improper calculation of overlap of A Delay and B Delay when determining PTA for each of the Novartis Patents was contrary to law as evidenced by the Wyeth decision.

68. Defendant's determination of PTA for each of the Novartis Patents was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law within the meaning of 5 U.S.C. § 706(2)(A); contrary to Novartis' constitutional rights within the meaning of 5 U.S.C. § 706(2)(B); and in excess of statutory authority within the meaning of 5 U.S.C. § 706(2)(C).

69. Defendant's determination of PTA for each of the Novartis Patents was a final agency action that is reviewable by a district court in accordance with 5 U.S.C. § 704.

70. Novartis has adequately exhausted all of its administrative remedies under 35 U.S.C. § 154.

71. In the event the Court determines that Novartis may not seek recalculation of PTA for the Novartis Patents pursuant to 35 U.S.C. § 154 because it is time barred under 35 U.S.C. § 154(b)(4)(A), Novartis will be left with no adequate remedy at law.

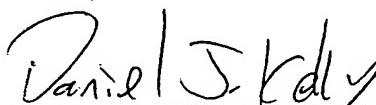
72. Novartis will suffer irreparable injury if Defendant is not directed to recalculate PTA for each of the Novartis Patents in accordance with Wyeth.

73. An order directing Defendant to recalculate PTA for each of the Novartis Patents in accordance with Wyeth would not substantially injure any other interested parties, and the public interest will be furthered by a recalculation of PTA for each of the Novartis Patents that is not contrary to law.

WHEREFORE, Novartis respectfully prays that this Court:

- A. Declare pursuant to 28 U.S.C. § 2201 that Defendant's determination of PTA for each of the Novartis Patents is invalid, unconstitutional and contrary to law;
- B. Issue an Order adopting the PTA for each of the Novartis Patents as set forth in Exhibit A, and requiring Defendant to revise the patent term of each of the Novartis Patents to reflect such PTA; and
- C. Grant such other and further relief as the nature of the case may admit or require and as may be just and equitable.

Respectfully submitted,



Daniel J. Kelly (DC Bar No. 397795)
McCARTER & ENGLISH, LLP
265 Franklin Street
Boston, MA 02110
Tel: 617-449-6526
Fax: 617-326-3088

Scott S. Christie
Mark H. Anania
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
Tel: 973-622-4444
Fax: 973-624-7070

*Attorneys for Plaintiffs Novartis AG and
Novartis Vaccines and Diagnostics, Inc.*

Owner and Assignee	Patent Number	PTA Granted	A Delay	B Delay	Overlap	C Reduction	Proper PTA	Additional Days
Novartis AG	6,656,957	567	567	5	0	0	572	5
Novartis AG	6,878,721	130	81	129	0	0	210	80
Novartis AG	7,098,325	389	517	326	153	111	579	190
Novartis AG	7,112,673	235	420	415	56	185	594	359
Novartis Vaccines and Diagnostics, Inc.	7,265,089	527	624	435	0	97	962	435
Novartis AG	7,348,353	176	296	295	63	120	408	232
Novartis AG	7,423,148	280	333	16	0	144	205	-75
Novartis Vaccines and Diagnostics, Inc.	7,470,709	392	602	419	0	210	811	419
Novartis AG	7,470,792	218	205	292	0	74	423	205
Novartis AG	7,534,890	520	609	267	0	89	787	267
Novartis Vaccines and Diagnostics, Inc.	7,576,221	141	306	153	0	222	237	96